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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,673	08/08/2003	Sarah R. Hertel	GEMS8081.178	1672
27061 7590 07/26/2007 ZIOLKOWSKI PATENT SOLUTIONS GROUP, SC (GEMS) 136 S WISCONSIN ST PORT WASHINGTON, WI 53074			EXAMINER KOZIOL, STEPHEN R	
			ART UNIT 2609	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/604,673

Applicant(s)

HERTEL ET AL.

Examiner

Stephen R. Koziol

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/10/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. **Claims 1, 2, 8-12, 15, 16, 18-20, 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Warfield et al. “Nonlinear Registration and Template Driven Segmentation,” June 1999, for the same reasons as set forth in the previous Office Action. (Grounds restated for convenience.)**

Regarding claim 1, Warfield et al. discloses a method of medical image overlap comprising the steps of:

- i. determining at least two anatomical fiducial markers on a functional image (pg. 1, par. 3, “...process that determines correspondence between data sets...”);
- ii. determining corresponding points to the at least two anatomical fiducial markers on an anatomical image (pg. 1, par. 3, “...process that determines correspondence between data sets...”);
- iii. aligning the at least two anatomical fiducial markers with the corresponding points on the anatomical image (pg. 1, par. 3); and

- iv. warping the functional image to fit constraints of the anatomical image while maintaining alignment of the at least two anatomical fiducial markers and the corresponding points on the anatomical image (pg.1, par. 3 "...warping' is used to refer to those matching techniques that involve the computation of a deformation field between points of correspondence...").

Regarding claim 2, Warfield et al. discloses method of medical image overlap further comprising the step of accessing a model of functional data prior to determining the at least two anatomical fiducial markers (pg. 8, par. 1 "validation experiments involving the recovery of a deformation field from a simple 3D model...").

Regarding claim 8, Warfield et al. discloses method of medical image overlap further comprising the step of determining the at least two anatomical fiducial markers includes the step of locating the at least two anatomical fiducial markers in a three-dimensional image (pg. 2, par. 7 "Matching techniques can be categorized by the form assumed for the computed transformation. A 3D geometric transform maps an image from the coordinate system...into a new image...").

Regarding claim 9, Warfield et al. discloses method of medical image overlap further comprising registering the functional image and the anatomical image by at least one of translating, scaling, and rotating the functional image and the anatomical image with respect to one another (pg. 2 par. 8 "Often a fixed model is chosen, and parameters of that model are then estimated.

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Examples include linear registration, where rotation, scaling, and translation parameters are usually estimated, as well as nonlinear models such as cubic transforms. ”).

Regarding claim 10, Warfield et al. discloses method of medical image overlap further comprising the step of enforcing anatomical constraints during the step of warping by projecting a nearest point on the functional image onto the anatomical image while maintaining surface smoothness. (pg.1, par. 3 “...’warping’ is used to refer to those matching techniques that involve the computation of a deformation field between points of correspondence...” and pg. 2 par. 8 “The nonlinear registration techniques compared here aim to compute high order mapping functions using local information, and *constrain the mapping functions* based on a physical model of elastic materials,” emphasis added).

Claim 11 has been analyzed and is rejected for the reasons outlined in claim 1 above. Although Warfield is silent on using a database to store the image data, such database image storage would have been inherently necessitated to achieve diagnostic image generation.

Claim 12 has been analyzed and is rejected for the reasons outlined in claim 9 above, as the limitations in claim 12 do not substantially differ from those in claim 9.

Claim 15 has been analyzed and is rejected for the reasons outlined in claim 8 above, as the limitations in claim 15 do not substantially differ from those in claim 8.

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Claim 16 has been analyzed and is rejected for the reasons outlined in claim 10 above, as the limitations in claim 16 do not substantially differ from those in claim 10.

Claims 18, 19 and 22 have been analyzed and are rejected for the reasons outlined in claim 1 above, as the limitations in claims 18, 19 and 22 do not substantially differ from those in claim 1 despite those limitations manifesting in a computer program.

Claim 20 has been analyzed and is rejected for the reasons outlined in claim 10 above, as the limitations in claim 20 do not substantially differ from those in claim 10.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in **Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966)**, that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows: (*See MPEP Ch. 2141*)

- a. Determining the scope and contents of the prior art;
- b. Ascertaining the differences between the prior art and the claims in issue;
- c. Resolving the level of ordinary skill in the pertinent art; and
- d. Evaluating evidence of secondary considerations for indicating obviousness or nonobviousness.

4. **Claims 3-7, 13-14, 17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Warfield et al. "Nonlinear Registration and Template Driven**

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Segmentation,” June 1999, further in view of Hasegawa, “Fusion Imaging with CT/SPECT” Imaging Economics, November/December 2000, for the same reasons as set forth in the previous Office Action. (Grounds restated for convenience.)

Regarding claim 3, Warfield et al. fails to further disclose a method of medical image overlap wherein the functional image includes perfusion data and the anatomical image includes anatomical data of a coronary artery. However, Hasegawa discloses that such a method of medical image overlap includes anatomical data of a coronary artery (pg. 5, par. 2 “...myocardial perfusion measurements for patients with cardiovascular or coronary artery disease.”).

Therefore, the combined teaching of Warfield and Hasegawa would have rendered obvious utilization of a including anatomical data of a coronary artery as claimed for the benefit of achieving medical image overlap.

Regarding claim 4, Warfield et al. fails to further discloses method of medical image overlap further comprising anatomical fiducial markers and the corresponding points on the anatomical image correspond to ventricle grooves between ventricles of a medical patient. However, Official Notice is taken that both the concept and advantage of anatomical fiducial markers and the corresponding points on the anatomical image correspond to ventricle grooves between ventricles of a medical patient are notoriously well known and expected in the art, and therefore would have been obvious to incorporate in Warfield’s disclosed method for the benefit of achieving medical image overlap on data of a coronary artery.

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Regarding claim 5, Warfield et al. fails to disclose a method of medical image overlap further comprising that data acquired with PET and the data acquired with CT include gated images.

However, Official Notice is taken that both the concept and advantage of acquiring gated image data using CT and PET scans are notoriously well known and expected in the art, and therefore would have been obvious to incorporate in Warfield's disclosed method for the benefit of achieving medical image overlap on data of a coronary artery.

Claims 6 and 13 have been analyzed and are rejected for the reasons outlined in claim 5 above, as the limitations in claim 6 and 13 do not substantially differ from those in claim 5.

Claim 14 has been analyzed and is rejected for the reasons outlined in claim 5 above, as the limitations in claim 14 do not substantially differ from those in claim 5.

Regarding claim 7, Warfield et al. fails to disclose in the method of medical image overlap that anatomical constraints of the functional image take into account cardiac motion. However, Hasegawa take into account cardiac motion (pg. 4, par. 1 "Differences in cardiac motion are averaged by acquiring the CT and SPECT studies over more than one cardiac cycle, while peristalsis is minimized by acquiring the x-ray and radionuclide images in rapid succession."). Therefore, the combined teaching of Warfield and Hasegawa would have rendered obvious utilization of take into account cardiac motion in the anatomical constraints of the functional image as claimed for the benefit of achieving medical image overlap.

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Claim 17 has been analyzed and is rejected for the reasons outlined in claim 4 above, as the limitations in claim 17 do not substantially differ from those in claim 4.

Claim 21 has been analyzed and is rejected for the reasons outlined in claim 5 above, as the limitations in claim 21 do not substantially differ from those in claim 5.

Examiner's Note

5. The referenced citations made in the rejection(s) above are intended to exemplify areas in the prior art document(s) in which the examiner believed are the most relevant to the claimed subject matter. However, it is incumbent upon the applicant to analyze the prior art document(s) in its/their entirety since *other areas of the document(s) may be relied upon at a later time to substantiate examiner's rationale of record*. A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). However, "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

Response to Arguments

6. Applicant's arguments filed July 10, 2007 have been fully considered but they are not persuasive.

With respect to claim 1, applicant alleges that Warfield fails to disclose the types of images required, the step of alignment, and the specific step of warping. Applicant also alleges that Warfield fails to teach or suggest aligning and warping of a functional image with an anatomical image. Applicant also alleges Warfield fails to disclose the claimed step of aligning because there is no teaching of determining markers on one image, determining points on another image, and then aligning said markers and points on the images. Finally, Applicant alleges Warfield fails to teach warping a functional image to fit constraints of an anatomical image while maintaining alignment of markers from the functional image with corresponding points on the anatomical image.

Examiner respectfully disagrees.

With respect to applicant's allegation that Warfield fails to teach or suggest aligning and warping a functional image with an anatomical image (Remarks pp. 6), Warfield teaches and certainly suggests in par. 2 of page 1 that both anatomical (anatomical variability brain mapping scans) and functional ("functional images") images are the kinds of images used for alignment and subsequent warping. See Examiner's Note as provided in the original Office Action and repeated supra where "*other areas of the document(s) may be relied upon at a later time to*

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substantiate examiner's rationale of record." Therefore the original grounds for rejection are maintained.

With respect to applicant's allegation that Warfield fails to disclose the claimed step of aligning because there is no teaching of determining markers on one image, determining points on another image, and then aligning said markers and points on the images (Remarks pp. 6-7), Warfield does disclose in par. 3 of page 1 that "matching" is used to refer to "any process that determines correspondences between data sets," where the "data sets" refer to the functional and anatomical images as established in par. 2 of page 1. Matching is further elaborated upon in par. 3 of page 3, where "matching...determine[s] a linear registration to globally align the model with the patient scan," which is certainly the equivalent of applicant's claimed "determining markers on one image, determining points on another image, and then aligning said markers and points on the images." Therefore the original grounds for rejection are maintained.

With respect to applicant's allegation that Warfield fails to teach warping a functional image to fit constraints of an anatomical image while maintaining alignment of markers from the functional image with corresponding points on the anatomical image (Remarks pp.7), Warfield does teach said warping in par. 3 of page 1, where warping refers to techniques "that involve the computation of a deformation field between points of correspondence." Furthermore, in par. 8 of page 2, Warfield teaches that alignment is maintained (mapping function constraint) when bringing markers of a functional image into alignment with corresponding points on the anatomical image. Therefore the original grounds for rejection are maintained.

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Applicant notes that claim 1's grounds for rejection are also applied to independent claims 11 and 18. Hence, for the reasons explained re claim 1 supra the original rejections to claims 11 and 18 are maintained.

With respect to dependent claims (2-10, 12-17, and 19-22), applicant does not raise further issue, and instead relies upon arguments re independent claims (1, 11, and 18), which have been refuted above. Therefore the original grounds for rejection for dependent claims (2-10, 12-17, and 19-22) are maintained.

With further respect to dependent claims (3 and 7) applicant does not raise issue with Examiner's use of secondary reference (Hasegawa) as applied to the 103(a) rejection of claims (3 and 7). Therefore, applicant acknowledges that secondary reference (Hasegawa) was properly combined with primary reference (Warfield) in forming the 103(a) rejection for claims (3 and 7).

Furthermore, applicant does not challenge Examiner's use of Official Notice as applied to claims (4-6, 13-14, 17, and 21). Therefore, applicant acquiesces to the fact that all subject matter contained in claims (4-6, 13-14, 17, and 21) is notoriously well known and expected in the art.

For the reasons above, all 102 and 103 rejections as set forth in the last Office Action stand.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Contact

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steve Koziol whose telephone number is (571) 270-1884. The examiner can normally be reached on M - alt. F 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vu Le can be reached on (571) 272-7332. Customer Service can be reached at (571) 272-2600. The fax number for the organization where this application or proceeding is assigned is (571) 273-7332.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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